GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4174
ANSWERED ON:11.08.2017
Mandatory Test for all Drugs
Patil Shri A.T. (Nana)

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government has made bio-equivalence studies or tests mandatory for all drugs before they are launched in the market;

(b) if so, the details thereof; and

(c) the details of steps taken by the Government to ensure generic medicines have the same quality and efficacy as their branded counterparts?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)
(a) & (b): Drugs & Cosmetics Rules, 1945 were amended vide GSR No.327 (E) dated 03.04.2017, stipulating a requirement that "the applicant shall submit the result of bioequivalence study referred to in Schedule Y, along with the application for grant of a license of oral dosage form of drugs specified under category II and category IV of the biopharmaceutical classification system".
(c): All the drugs manufactured in the country, whether branded or generic, are required to comply with the same standards prescribed in the Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945 made thereunder.
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